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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,243	01/31/2000	Reid Warren von Borstel	1331-300	3188

23117 7590 08/13/2003

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EXAMINER
OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
1623	13

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/494,243	VON BORSTEL ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Arguments

The following is in response to the amendment filed 5/19/03:

An action on the merits of claims 47-54 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 112(1)

Applicant's arguments filed 5/19/03 have been fully considered but they are not persuasive. The rejection of claims 47-54 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record, set forth below.
A written description analysis involves three principle factors:

1. Field of the invention and predictability of the art
2. Breadth of the claims
3. For each claimed species/genus, possession of the claimed invention at the time of filing.

The breadth of the claim is such that cellular damage caused by any mutagenic substance may be prevented or treated. The specification presents dosages for the treatment of radiation induced cellular damage or sunburn with the compounds of the invention (p.34). The specification states that the acylated deoxyribonucleosides may prevent radiation induced cellular damage. However, a statement of a potential effect does not constitute a sufficient written description for prevention; moreover, the support in the specification is not adequate for the claim to the treatment or prevention of cellular damage caused by any mutagen.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by functional characteristics sufficient to show the applicant was in possession of the claimed genus. There are a variety of mutagenic substances; base analog mutagens, alkylators, uv mutagenesis, nitrous acid, ICR compounds, etc. each with a certain degree of specificity. There is limited predictability in the art that any one compound or class of compounds is capable of preventing or treating cellular damage from a variety of mutagenic substances. To provide adequate support to the breadth of the claims, applicant would have to establish that over a period of time, a population of individuals subjected to a variety of the types of mutagenic substances cited above, were treated for or did not incur any cellular damage. The data presented shows mortality rates after exposure to gamma radiation which may be adequately correlative for the species of treating radiation induced cellular damage; however, this does not correlate to a prevention or treatment of cellular damage caused by any mutagen as broadly claimed. A representative number of species requires that the species which are expressly described be representative of the entire genus and what constitutes a "representative number" is an inverse function of the predictability of the art. As such, a skilled artisan would not recognize that a compound capable of treating radiation induced cellular damage would be representative in function to the prevention and treatment of the genus of mutagens as broadly claimed. As such, there is not seen any data which supports applicant's claim that at the time of filing, the application/administration of the compounds of the invention was applied to a population of individuals exposed to a variety of mutagens which could promote damage, and cellular damage was prevented or treated.

Applicant's primary argument is that data or other support is nor required to satisfy the written description requirement. However, as cited supra, one of the three considerations for a written description requirement is: For each claimed species/genus, possession of the claimed invention at the time of filing. The term data in this case is actually synonymous with applicant's demonstration that they were in possession of an invention wherein cellular damage was prevented for a broad class of mutagen species, i.e. base analog mutagens, alkylators, uv mutagenesis, nitrous acid, ICR compounds,

etc. In the response, applicant does not provide any of these relevant species to constitute possession of the breadth of species encompassed by the term mutagen; moreover, there is no instance wherein cellular damage by these species is prevented. Applicant seems to assert that by simply using the term mutagens in the specification, that constitutes possession.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by functional characteristics sufficient to show the applicant was in possession of the claimed genus. The response does not present any evidence to show that the representative number of mutagen species were sufficiently described in the context of prevention. As cited from p.12 of the *Interim Guidelines for the Examination of Patent Applications of 35 U.S.C. 112(1) Written Description Requirement*, 6/4/98, p.12, " A representative number of species requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a description of the various species which reflect the variation within the genus." Clearly there is substantial variation between radiation as a mutagen versus a chemical mutagen such as an alkylator or nitrous acid. Applicant should note that the claimed invention for the prevention of cellular damage from the genus of mutagens is not satisfied by the mere recitation of the genus "mutagens" in the specification. Applicant has provided no evidence in the response that the specification possessed a demonstration of the invention with regards to prevention within this substantial variation of species; moreover, there isn't even a recognition of the variability of mutagen species and the prevention therefor within the specification.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.